UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 26, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 83135-R
DP Barcode: D342113

To: Velma Noble\Jacqueline Campbell-McFarlane
Regulatory Management Branch I
Antimicrobials Division (7510P)

From: Chris Jiang, Chemist
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

Applicant: Coatings Specialist Group

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s):	
3-(trihydroxysilyl) propyl dimethyl octadecyl ammonium chloride	1.44 %
Inert Ingredient(s):	98.56 %
Total:	100 %

BACKGROUND: The registrant has submitted an acute toxicity package for an end-use product to be used as a biostatic agent. The acute toxicity package includes studies that have been submitted to and identified by the Agency as MRIDs 47169202, 47169203, 47169204, 47169205, 47169206, and 47169207. The contractor has done the primary review of this submission and Product Science Branch of Antimicrobials Division has done a secondary review of this submission which supersedes the primary review.

RECOMMENDATIONS: PSB findings are:

1. The current acute toxicity profile of 83135-R is:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Acceptable
eye irritation	IV	Acceptable
skin irritation	IV	Acceptable
skin sensitization	Nonsensitizer	Acceptable

LABELING

The optional signal word is **CAUTION**; however, the signal word is not required because this product has toxicity category IV for all of the acute toxicity requirements.

No precautionary or first aid statements are required because this product has toxicity category IV for all of the acute toxicity requirements.

The precautionary statements may read, "Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes, or clothing. Wear goggles or face shield, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse."

The first aid statements may read:
IF IN EYES
-Hold eye open and rinse gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.
IF INHALED
-Move victim to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
-Call a poison control center or doctor for further treatment advice.

IF ON SKIN OR CLOTHING

-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

IF SWALLOWED

-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by a poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1, 870.1100)

Product Manager: Velma Noble
MRID No.: 47169205

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10790-07

Testing Laboratory: Stillmeadow Inc.
Author: Janice O. Kuhn

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Dosage: 5000 mg/kg

Species: Three female Sprague-Dawley CFY rats
Age: Five to eight weeks
Weight: ♀: 188-194 g
Source: Texas Animal Specialties, Humble, TX

Conclusions:

1. **LD_{50} (mg/kg):** **Males** > 5000 mg/kg
   Females > 5000 mg/kg
   Combined > 5000 mg/kg
2. **The estimated LD_{50} is greater than 5000 mg/kg.**
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from 81-1): The Up and Down Procedure was used. Females were used because they are often the more sensitive sex.

Results:

Dosage (mg/kg)	Mortality
5000	0/3

Observations: All animals appeared normal for the duration of the study.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2, 870.1200)

Product Manager: Velma Noble
MRID No.: 47169206

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10791-07

Testing Laboratory: Stillmeadow Inc.
Author: Janice O. Kuhn

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Dosage: 5050 mg/kg

Species: Five male and five female Sprague-Dawley albino rats
Age: Two months
Weight: ♂: 275-281 g; ♀: 188-208 g
Source: Texas Animal Specialties, Humble, TX

Conclusions:

1. **LD_{50} (mg/kg):** **Males** > 5050 mg/kg
   Females > 5050 mg/kg
   Combined > 5050 mg/kg
2. **The estimated LD_{50} is greater than 5050 mg/kg.**
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from 81-2): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5050	0/5	0/5	0/10

Observations: All animals appeared normal for the duration of the study.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (81-3, 870.1300)

Product Manager: Velma Noble
MRID No.: 47169207

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10792-07

Testing Laboratory: Stillmeadow Inc.
Author: Vicki Crutchfield

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Dosage: 2.21 mg/L

Species: Five male and five female Sprague-Dawley albino rats
Age: Two months
Weight: ♂: 299-336 g; ♀: 193-226 g
Source: Texas Animal Specialties, Humble, TX

Summary:

1. **LC_{50} (mg/L):** **Males**: > 2.21 mg/L
   Females: > 2.21 mg/L
   Combined: > 2.21 mg/L
2. **The estimated LC_{50} is greater than 2.21 mg/L.**
3. **MMAD**: 2.5 µm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From 81-3): No deviations occurred during the study.

Results:

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER OF DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.21	0/5	0/5	0/10

Concentration

Nominal Chamber Concentration (mg/L)	Gravimetric Chamber Concentration (mg/L)
35.4	2.21

Particle size distribution				
Exposure concentration (mg/L)	Average MMAD (µm)	Average GSD (µm)	% Particles *	
			≤ 0.5 µm	≤ 0.3 µm
2.21	2.5	6.9	16	16

*-percentage determined by two air samples

Chamber Environment	
Chamber Volume	500 L
Airflow	187 Lpm
Temperature	21.2 to 21.7 °C
Relative Humidity	60.9 to 61.9 %

Clinical Observations: The clinical signs included hypoactivity and piloerection.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Velma Noble
MRID No.: 47169202

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10793-07

Testing Laboratory: Stillmeadow Inc.
Author: Janice O. Kuhn

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Dosage: 0.1 g

Species: One male and two female New Zealand White albino rabbits
Weight: ♂: 3.200 kg; ♀: 2.400-2.500 kg **Age**: Four months
Source: Nichols Rabbitry Inc., Lumberton, TX

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From §81-4): No deviations occurred during the study.

Results:

Observations	Rabbit No.: 1388				Rabbit No.: 1389				Rabbit No.: 1393			
	Hours				Hours				Hours			
	1	24	48	72	1	24	48	72	1	24	48	72
I. Corneal Opacity	0	0	0	0	0	0	0	0	0	0	0	0
II. Iris	0	0	0	0	0	0	0	0	0	0	0	0
III. Conjunctivae												
A. Redness	1	0	0	0	1	1	1	0	1	1	1	0
B. Chemosis	0	0	0	0	1	0	0	0	1	1	1	0

Flourescein staining was used after the 24-hour observation to test for the presence of corneal opacity

DATA REVIEW FOR PRIMARY SKIN IRRITATION TESTING (81-5, 870.2500)

Product Manager: Velma Noble
MRID No.: 47169203

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10794-07

Testing Laboratory: Stillmeadow Inc.
Author: Janice O. Kuhn

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Dosage: 0.5 g

Species: One male and two female New Zealand White albino rabbits
Weight: ♂: 2.425 kg; ♀: 2.500-2.875 kg **Age**: Four months
Source: Nichols Rabbitry Inc., Lumberton, TX

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From 81-5): No deviations occurred during the study.

Results:

Animal Number	Draize score for erythema/edema after patch removal			
	1 hr	24 hr	48 hr	72 hr
1398	0/0	0/0	0/0	0/0
1399	0/0	0/0	0/0	0/0
1401	0/0	0/0	0/0	0/0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (81-6, 870.2600)

Product Manager: Velma Noble
MRID No.: 47169204

Reviewer: Chris Jiang
Study Completion Date: June 21, 2007
Report No.: 10795-07

Testing Laboratory: Stillmeadow Inc.
Author: Janice O. Kuhn

Quality Assurance (40 CFR §160.12): A statement of GLP compliance was included.

Test Material: Sportsaide 1000, clear liquid
Positive Control Material: 1-Chloro-2,4,-dinitrobenzene

Species: Fifteen male and fifteen female Hartley albino guinea pigs
Weight: ♂: 341 to 410 g; ♀: 312 to 375 g **Age**: Two months
Source: Charles River Laboratories, Wilmington, MA

Method: Modified Buehler

Summary:

1. **This Product is not a dermal sensitizer.**
2. **Classification**: Acceptable

Procedure (Deviation From 81-6): No deviations occurred during the study.

Procedure: After a preliminary range-finding study, the definitive study was undertaken. Once each week for three weeks, either nothing or 0.4 mL of the undiluted test material was applied to the clipped left side of each animal using surgical gauze patches that were secured with strips of non-irritating adhesive tape which were placed over strips of polyethylene film. After application of the dressings, the trunks of the animals were wrapped with elastic wrap which was secured with adhesive tape. After the six-hour exposure period, the dressings and gauze patches were removed and the test sites were cleansed of residual test substance. The guinea pigs were scored at 24 and at 48 hours after the first induction and 24 hours after the second and third inductions.
Two weeks after the third induction, all animals were challenged with 0.4 mL of the undiluted test substance. The guinea pigs were scored at 24 and at 48 hours after challenge.

Results: None of the animals showed any dermal irritation at any of the observation periods.

The positive control showed appropriate results.